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Gail E. Poulos
USDA-ARS-OTT
5601 Sunnyside Avenue, Rm. 4-1183
Beltsville, Maryland 20705-5131

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,135,759

Dear Ms. Poulos :

An interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 5,135,759 for a period of one year from the original expiration date, i.e., until August 4, 2010. A copy of the Federal Register notice, published on August 4, 2009 at 74 Fed. Reg. 38585, regarding the issuance of the interim extension under 35 U.S.C. § 156(d)(5) is also enclosed. While a courtesy copy of this letter is being sent to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates which are pertinent to any filings before the FDA.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: MicroSort® Sperm Separation
Technology
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States of America as represented

by the Secretary of Agriculture

Request for Patent Term Extension

U.S. Patent No. 5,135,759

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: **ORDER GRANTING**

: **INTERIM EXTENSION**

On June 8, 2009, patent owner, United States of America, as represented by the Secretary of Agriculture, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,135,759. The patent claims a use of the medical device, the MicroSort® Sperm Separation Technology. The application indicates, and the Food and Drug Administration has confirmed, that a Premarket Approval application (P090004) for the MicroSort® Sperm Separation Technology has been filed by the licensee of the patent owner, Genetics & IVF Institute, and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the original expiration date of the patent (August 4, 2009), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 5,135,759 is granted for a period of one year from the expiration date of the patent, i.e., until August 4, 2010.

07/28/09
Date

John J. Doll
John J. Doll
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office